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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,117	12/30/2003	David M. Gravett	110129.434	3276

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EXAMINER	
ROGERS, JAMES WILLIAM	
ART UNIT	**PAPER NUMBER**
1618	
MAIL DATE	**DELIVERY MODE**
09/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/749,117	GRAVETT ET AL.	
	Examiner	Art Unit	
	James W. Rogers, Ph.D.	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07/17/2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,14-75,84,87-104,106-112 and 127-129* is/are pending in the application.

4a) Of the above claim(s) *7-9,11-12,15,16,22-74,100,101,103 and 104* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,10,14,17-21,75,84,87-99,102,106-112 and 127-129* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/17/2007 has been entered.

Response to Amendment

The amendment to the claims filed 07/17/2007 has been entered, applicants have amended claims 1,84,89-93,106 and 110 added new claim 127-129 and cancelled claims 85-86 and 105.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Specification

The specification on page 112 line 28 is objected to because of the following informalities: "be" is refereeing to polymer component "B" of the block copolymer and should be changed accordingly. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 93 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically the wording at line 6-7 which states "at least one sulfhydryl reactive-group containing compound either a liquid medium having a neutral pH or in a powder form" is indefinite and not in proper grammatical form. It appears as though applicants intended to state the sulfhydryl-containing compound is present in either a liquid medium or in a powdered form and was examined using that interpretation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6,10,14,17-21,75, 84,87-99,102,106-112 and 127-129 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wallace et al. (US 6,312,725, disclosed by applicants) in view of Shih et al. (US 6,287,588).

Wallace discloses rapid gelling (<1 min) biocompatible polymer compositions that can be used for *in vivo* administration that are comprised of two components, the first is a nucleophilic PAO containing 4-12 sulfhydryl nucleophilic groups and the second is an electrophilic PAO which can contain a mixture of between 4-12 succinimidyl and maleimidyl electrophilic groups, the composition can further contain other materials such as drugs, antibiotics and methylated collagen. See abstr, col 1 lin 66-col 2 lin 60, col 4 lin 8-67, col 5 lin 9-col 6 lin 8, col 8 lin 9-23, col 10 lin 55-col 11 lin 2, examples and claims. Wallace also discloses that the nucleophilic polymer can be contained in an alkaline buffer solution of sodium phosphate/carbonate within the pH range specified by applicants and the electrophilic polymer can be contained in an acidic buffer solution. See col 9 lin 12-45 and examples. Each component of the composition is administered

separately to the tissue site or both together, then within a short time after being mixed together at the site of administration the composition forms a gel, this statement in the Wallace patent meets the limitations in claim 89 that the first and second component are administered sequentially or subsequently, the drug is contained within the PAO gel. See col 3 lin 25-32 and examples.

Wallace while disclosing that the gels can comprise drugs the patent is silent on the use of microspheres that incorporate drugs such as paclitaxel.

Shih discloses an agent delivery system comprised of a microparticle (including microspheres) and a biodegradable gel, the drug including paclitaxel which is included in both the microparticle and the gel. See abstract, claims 1-3,16-19 and 27. Regarding new claim 127 the microparticles of Shih were preferably comprised of biodegradable polyesters and copolymers thereof, especially polymers of poly(D,L-lactide-co-glycolide). See col 6 lin 12-32 and examples. Claims 128-129 limit the copolymer to a block containing a biodegradable ester and PEG and/or PPO, Shih specifically discloses that the biodegradable polyesters could be block copolymers and Shih used pluronic PEO-PPO-PEO microparticles in the examples, therefore from the disclosure of Shih it would have been obvious to try a copolymer containing a polyester and PEO-PPO-PEO.

It would have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to combine the art described in the documents above because Wallace discloses all that is claimed within applicants current application but is silent on the use of drug containing microspheres while Shih discloses that it was well

known in the art to use microspheres containing drugs within biocompatible gels. One with skill in the art would have a reasonable expectation of success in combining the two reverences above because both are related to the same field of endeavor, biocompatible gels that controllably release active agents and the combination would have yielded predicable results to one of ordinary skill in the art. The motivation to combine the above documents would be to form a rapidly forming adhesive gel formulation containing microspheres for controlled drug delivery with the disclosed advantages of the references above for treating tissues. The advantage of such a composition would be a controlled release of drug using the microspheres disclosed within Shih for tissue treating applications requiring rapid adhesion by the polymer gels of Wallace. Thus, the claimed invention, taken as a whole was *prima facie* obvious over the combined teachings of the prior art.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER